DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

MN2210n

PURGED RFK

November 9, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 03

Arthur R. Kydd
President
Diabetes Control and Care Technology, Inc.
10180 Viking Drive
Eden Prairie, Minnesota 55344

Dear Mr. Kydd :

We are writing to you because on October 8-21, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the blood glucose monitoring systems that are manufactured at your facility in Eden Prairie, Minnesota.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. They are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), in the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of medical devices.

Our inspection found your products violate the law because they do not conform to the requirements as follows:

1. Failure to establish and maintain process control procedures to ensure conformance to specifications (21 CFR 820.70). For example, blood glucose test strips lot numbers 40125, 40123, 40124A, 40126A, 40126B, 40126, 20120, 20121, and 50112 were distributed despite performance test results that were outside of your firm's specifications (form FDA-483 item 1);

2. Failure to establish and maintain procedures to control product that does not conform to specified requirements and define the responsibility for review and the authority for the disposition of non-conforming product, including documentation of the justification for use of non-conforming product (21 CFR 820.90). For example, there is no formalized written re-test procedure for glucose test strips that fail to meet in-process specifications (form FDA-483 item 4);

3. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100(a)]. For example, your firm lacks procedures for investigating the cause of non-conformities relating to product, processes, and other quality problems (form FDA-483 item 2) and for identifying the action(s) needed to correct and prevent recurrence of non-conforming product (form FDA-483 item 3); and

4. Failure of you and your management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of 21 CFR 820.20 and your established quality policy and objectives (form FDA-483 items 5 and 6).

In legal terms, the products are adulterated under Section 501(h) of the Act.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the form FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

We received your letter dated October 27, 1998, addressing the concerns referenced on the form FDA-483 issued on October 21, 1998. Regarding your response, we have the following comments:

FDA-483 item 1: It should be stressed that, all other issues aside, the distribution of out-of-specification product followed a failure to follow your own standard procedures for finished product acceptance testing and the lack of procedures for dealing with non-conforming product.

FDA-483 item 2: Your response does not address establishing and implementing procedures for performing failure investigations.

FDA-483 item 3: The procedures should also describe the actions to be taken when test data are not within specifications.

FDA-483 items 4, 5 and 6: These responses are satisfactory.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, the most responsible individual at Diabetes Control and Care Technology, Inc., it is ultimately your responsibility to ensure that devices

manufactured at your facility in Eden Prairie, Minnesota, are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Quality System Requirements for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at *http://www.fda.gov*.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,

James A. Rahto
Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 10/21/98